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Medivators DSD Edge Endoscope Reprocessing System

APR - 5 2010

510(k) Summary of Safety and Effectiveness

Manufacturer: Medivators Reprocessing Systems, A Division of Minntech Corporation

Address: 14605 28th Avenue North
Minneapolis, MN 55447 USA
Establishment Registration No: 2150060

Official Contact: Richard M. Ormsbee
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Minntech Corporation
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Device Identification:

- Device Trade Name: Medivators DSD Edge Endoscope Reprocessing System
- Common Name: Endoscope washer/disinfector
- Class II
- Regulation Number/Name 876.1500 Endoscope and accessories
- Product Code FEB – Accessories, Cleaning, For Endoscope

Medivators has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalence of the DSD Edge Endoscope Reprocessing System to other endoscope reprocessors and high level disinfectants currently marketed in the U.S.

1. **Device Description**

   The DSD Edge system is an electro-mechanical system intended to test, wash and high level disinfect flexible fiberoptic and video endoscopes between uses. The DSD Edge is capable of asynchronously reprocessing two scopes at a time.

   The DSD Edge system uses the peracetic acid based Rapicide PA High Level Disinfectant (K082988). The DSD Edge is a single use system in that it mixes Part A and Part B of Rapicide PA with water immediately prior to reprocessing and the disinfectant is not reused.

Date Prepared: 3-29-2010

Endoscopes must be pre-cleaned and manually cleaned to SGNA and facility guidelines prior to being placed in the system for reprocessing.

After the endoscopes are connected to the DSD Edge the system tests the scopes for leaks in the outer skin. If the endoscopes pass the leak test the system will proceeds to a scope flush or an optional wash cycle followed by a flush.

For the disinfection cycle, the incoming water is mixed with the two part germicide in the basin. The temperature of the incoming water is monitored to ensure that the water temperature is within the operating constraints (30°C) required for disinfection after the water and germicide are mixed together. A sample of the germicide is retained to test for MRC. Following disinfection, the endoscopes are rinsed and dried by the machine, either by filtered air or an optional alcohol rinse, and are then removed from the machine for the next use.

The machine has built in safety features which stop the cycle and alarm when certain conditions exist which could indicate that disinfection might be compromised. These alarms and causes are defined in the directions for use for the product.

The DSD Edge also prints records indicating the results of testing, disinfection, etc. which are required for permanent records.

2. Indications for Use Statement

Medivators DSD Edge Endoscope Reprocessing System tests, washes, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The DSD Edge system is indicated to provide high level disinfection, using Rapicide PA High Level Disinfectant, of heat sensitive semi-critical endoscopes. Manual cleaning of endoscopes is required prior to placement in the DSD Edge system.

Rapicide PA contact conditions in the DSD Edge

- 5 Minutes - 30°C - 850 ppm peracetic acid

3. Comparison to Another Device in Commercial Distribution Within the United States

The DSD Edge is equivalent in function and indications to the Medivators Advantage Plus Endoscope Reprocessing System (K082988) and the Medivators DSD 91 Disinfector for Flexible Endoscopes (K914145). All of the machines have the same indications for use and the same methods for providing disinfection.

4. Summary of Testing

Medivators has provided testing to show that the DSD Edge Endoscope Reprocessing System is safe and effective for its intended use following the requirements listed in the FDA's Guidance on Premarket [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (dated August 1993).

Material Compatibility

The effect of the disinfectant on materials used in the DSD Edge system was evaluated and showed that the system materials showed no significant deterioration over time. Studies were also presented to show that the filters used in the water filtration system were compatible with the disinfectant.

Biocompatibility

The amount if disinfectant residue left on endoscopes after the disinfection and rinsing cycles was evaluated and compared to determine safe levels. The results of the testing showed that any remaining residues would not have an effect on patients or users.

Performance Data

Data was provided to the FDA to show that the machine performs as required. This evaluation included testing to show that the leak check, washing cycle, disinfection cycle, rinse cycles and drying cycles performed correctly. Any error messages were tested to ensure they function properly to notify users of any possible failure modes.

Testing was provided that showed the disinfectant remained at its required temperature for the length of time required for high level disinfection.

Testing was completed that showed the DSD Edge self disinfection cycle works properly by disinfecting all areas of the machine, including the water filtration system.

5. Summary of Substantial Equivalence

Medivators has provided the above information in the form of a 510(k) to support the claim that the DSD Edge Endoscope Reprocessing System is safe and effective when used in accordance with the device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Richard M. Ormsbee
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Minntech Corporation
14605 28th Avenue North
Minneapolis, Minnesota 55447-4822

APR - 5 2010

Re: K092387
Trade/Device Name: Medivators DSD Edge Endoscope Reprocessing System
Regulation Number: 21CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: March 30, 2010
Received: March 31, 2010

Dear Mr. Ormsbee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K092387

Device Name: Medivators DSD Edge Endoscope Reprocessing System

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Prescription Use _____ AND/OR
(Part 21 CFR 801 Part D)

Over-the Counter Use _X_
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092387